



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of a Start-Up Exclusive Patent License Agreement: Use of compounds covered by Patent Rights for diagnosis of human thyroid cancer requiring FDA premarket approval or an equivalent authority outside of the United States, and treatment of human thyroid cancer

AGENCY: National Institutes of Health, HHS

ACTION: Notice

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of a Start-Up Exclusive Patent License to Nova Therapeutics LLC, a company having a place of business in Delaware, to practice the inventions embodied in the following patent applications:

- a) PCT Patent Application No. PCT/US2008/11958
Filed: October 20, 2008
HHS Ref. No.: E-284-2008/0-PCT-01
- b) Australian Patent No. 2008-363295
Filed: October 20, 2008
HHS Ref No.: E-284-2008/0-AU-02

- c) Canadian Patent Application No. 2,741,030
Filed: October 20, 2008
HHS Ref. No.: E-284-2008/0-CA-03
- d) European Patent Application No. 08876356.0
Filed: October 20, 2008
HHS Ref. No.: E-284-2008/0-EP-04
- e) Indian Patent Application No. 3684/DELNP/2011
Filed: October 20, 2008
HHS Ref. No.: E-284-2008/0-IN-05
- f) Japanese Patent Application No. 2011-532048
Filed: October 20, 2008
HHS Ref. No.: E-284-2008/0-JP-06
- g) U.S. Patent No. 8,741,259
U.S. Patent Application No. 13/125,045
Filed: October 20, 2008
HHS Ref. No.: E-284-2008/0-US-07
- h) U.S. Patent Application No. 13/897,330
Filed: October 20, 2008
HHS Ref. No.: E-284-2008/0-US-08
Current status: pending
- i) U.S. Patent Application No. 14/243,821
Filed: October 20, 2008
HHS Ref. No.: E-284-2008/0-US-10

The patent rights in this invention have been assigned to the Government of the United States of America. The territory of the prospective Start-Up Exclusive Patent License Agreement may be worldwide and the field of use may be limited to: Use of compounds covered by Patent Rights for diagnosis of human thyroid cancer requiring FDA premarket approval or an equivalent authority outside of the United States, and treatment of human thyroid cancer.

DATES: Only written comments or applications for a license (or both) which are received by the NIH Office of Technology Transfer on or before [Insert date 15 days from date of publication of notice in the FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated Start-Up Exclusive Patent License Agreement should be directed to: Lauren Nguyen-Antczak, Ph.D., J.D., Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-4074; Facsimile: (301) 402-0220; E-mail: Lauren.Nguyen-antczak@nih.gov. A signed confidentiality nondisclosure agreement will be required to receive copies of any patent application(s) that have not been published or issued by the United States Patent and Trademark Office of the World Intellectual Property Organization.

SUPPLEMENTARY INFORMATION: This invention concerns small molecule compounds that agonize the activity of the thyroid stimulating hormone receptor (“TSHR”). These TSHR agonists enhance or activate the thyroid stimulating hormone (“TSH”) signaling pathway by directly binding to the transmembrane domain of TSHR. Invention compounds may be administered alone or in combination with radioactive iodine to detect thyroid cancer cells. Additionally, invention compounds may be administered in combination with radioactive iodine to treat thyroid cancer, such as to ablate thyroid remnants in patients after a thyroidectomy.

The prospective Start-Up Exclusive Patent License that is being considered can be found at <http://www.ott.nih.gov/forms-model-agreements#SUMLA>, which complies with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404. The prospective Start-Up Exclusive Patent License is being provided under the small business initiative launched on 1 October 2011. The prospective Start-Up Exclusive Patent License may be granted unless the NIH receives written evidence and argument, within fifteen (15) days from the date of this published notice, that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Complete applications for a license in the prospective field of use that are filed in response to this notice will be treated as objections to the grant of the contemplated Start-Up Exclusive Patent License. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: December 4, 2014

Richard U. Rodriguez, M.B.A.
Acting Director
Office of Technology Transfer
National Institutes of Health